UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO., LTD., Plaintiffs, v. RICHARD HART and MARIE LOUISE TRUDEL-HART, Defendants.	Civil Action No. 12-CV-3479 (SAS)

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE THE EXPERT REPORT AND TESTIMONY OF CARRIE M. KUEHN

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Plaintiffs Sekisui America Corporation and Sekisui Medical Co., Ltd. (together, "Sekisui" or "Plaintiffs") submit this opposition to Defendants Richard Hart and Marie Louise Trudel-Hart's (together, "Defendants") Motion *in Limine* to Exclude the Expert Report and Testimony of Carrie M. Kuehn ("Defs.' Mot.").

PRELIMINARY STATEMENT

Defendants have no legitimate basis to argue that Carrie Kuehn is not qualified to offer expert testimony in this case. Defendants never raised Ms. Kuehn's qualifications as a basis for excluding her testimony at the parties' September 27, 2013 pre-motion conference (they argued instead that she was offering legal conclusions), and indeed the Court stated at that conference that Ms. Kuehn ***is qualified***.

> I know your argument that it's a legal conclusion, but I don't think so. [Ms. Kuehn] has expertise in this area. She can comment and state that ADI was not in compliance with all applicable laws and regulations between 2006 and 2009. That's what experts do. So I don't see anything wrong with Kuehn either. So that's my views, initial views on all those.

(Declaration of Craig Whitney ("Whitney Decl."), Ex. A (Sept. 27, 2013 Tr.) at 16:24-17:4.)

Defendants' new argument in their current motion is, by their own admission, a defensive response to Plaintiffs' motion to exclude portions of the expert report and testimony of Defendants' expert, Thomas Becze. (*See* Defs.' Mot. at 5 ("By Plaintiffs' reasoning, Ms. Kuehn's report and testimony must also be excluded.")). But the situations are different. Plaintiffs' motion with regard to Mr. Becze is limited to excluding Mr. Becze's three-paragraph rebuttal summarily dismissing Timothy Ulatowski's 35-page expert report as "pure conjecture" and "pure speculation," when Mr. Becze did not even review the 510(k) submission that was the subject of Mr. Ulatowski's report, or explain how his lack of experience with the FDA's internal decision-making process regarding 510(k) submissions allowed him to reach the sweeping and unsupported conclusion that it is "impossible to predict the outcome of a 510(k) submission."

Defendants' motion, on the other hand, seeks to exclude the entire report and testimony of Ms. Kuehn merely by stating that, she too, did not work at the FDA. This is not what Plaintiffs are arguing with regard to Mr. Becze—and notably Plaintiffs are not attempting to exclude Mr. Becze's rebuttal of Ms. Kuehn on those same grounds. Moreover, Defendants' criticism of Ms. Kuehn ignores her 18 years of training and experience, including extensive experience in drug and medical device regulatory affairs. Ms. Kuehn specializes in FDA medical device regulatory affairs and submissions, Quality Systems Regulations, design control and regulatory compliance. She is respected in the industry, widely published and a frequent speaker at industry conferences. Ms. Kuehn's experience makes her eminently qualified to give testimony about FDA compliance and regulations, which the Court previously acknowledged, and which is the substance of her report and testimony in this case. In short, Defendants' motion *in limine* to exclude Ms. Kuehn's entire expert testimony is baseless and should be denied.

ARGUMENT

I. Defendants' Motion Is Nothing More Than an Attempt to Defend Their Own Expert's Shortcomings.

Defendants only sought to exclude Ms. Kuehn's expert report on the basis of her qualifications *after* Plaintiffs made their motion to exclude a portion of Mr. Becze's rebuttal report regarding his critique of a different expert. Plaintiffs adhered to the original November 1, 2013 filing deadline for their motion, but Defendants sought until November 4 for their motion, in part because Ms. Kuehn had supplemented her report pursuant to Federal Rule of Civil Procedure 26(e)(2) on October 18, 2013.[1] (*See* Whitney Decl., Ex. B (Oct. 24, 2013 Hearing Tr.)

[1] Ms. Kuehn included a memo with her supplemental report detailing the changes, which amounted to modest revisions based on additional materials she had reviewed. (*See* Declaration of Siobhan Briley in Support of Defendants' Motion in Limine (Dkt. No. 73) ("Briley Decl."), Ex. 15 (Kuehn Memo).) In any event, none of the changes in her supplemental report would have impacted whether she was qualified to provide the opinions in her report.

at 28:11-20, 31:13-24.) On November 4, Defendants submitted a letter to the Court stating for the first time that "The Harts will move in limine to exclude the Kuehn Report on the same grounds Plaintiffs assert for excluding the expert rebuttal report of Thomas C. Becze: Ms. Kuehn 'lacks any experience either with the FDA or [with FDA inspections], and fails to explain how whatever experience [s]he does have provide[s] a basis for [her] opinion' that ADI was not in regulatory compliance between 2005 and 2009." (Whitney Decl., Ex. C (Nov. 4, 2013 Letter) at 2.) As noted above and more fully in Plaintiffs' Motion i*n Limine* to Exclude Portions of the Expert Report and Testimony of Thomas D. Becze (Dkt. No. 65), Plaintiffs' motion is limited to Mr. Becze's cursory three-paragraph rebuttal of Mr. Ulatowski's report, and is based on several grounds. One of those grounds is Mr. Becze's failure to show how his experience allows him to opine that it is "impossible" for Mr. Ulatowski—a 36-year veteran of the FDA—to conclude that American Diagnostica, Inc.'s ("ADI") 2009 510(k) submission to the FDA for Femtelle premarket approval was destined to fail. This is particularly problematic when Mr. Becze admitted that he never even reviewed the 2009 Femtelle 510(k) submission at issue and that his opinion is not based on any specific documents related to the 2009 submission. The same argument does not apply to Ms. Kuehn's expert report, which is based on a careful review of thousands of ADI documents and discussions with ADI employees.

II. Defendants' Arguments to Exclude Ms. Kuehn Are Baseless.

Defendants argue that the entirety of Ms. Kuehn's testimony should be stricken because Ms. Kuehn is not a qualified expert and did not base her opinions on sufficient data. (Defs.' Mot. at 3, 5-6.) They purportedly base their motion on the same reasoning and legal authority cited by Plaintiffs in their motion to exclude the portion of Mr. Becze's proffered testimony rebutting Mr. Ulatowski's report. Defendants' argument regarding Ms. Kuehn is meritless.

A. Ms. Kuehn Is a Qualified Expert.

As the Court has previously recognized, Ms. Kuehn meets the standard required for an expert under Federal Rule of Evidence 702. Defendants' motion *in limine* is rife with things they assert Ms. Kuehn is not—she has not worked for the FDA, or she has not worked for a medical device manufacturing company, for example—and ignores the experience she has, including her extensive experience and qualifications in the field of FDA regulatory compliance.[2] Defendants fail to acknowledge that Ms. Kuehn is employed by a highly regarded consulting firm where her work focuses on FDA medical device regulatory affairs, including application of the Quality System Regulations, design control and regulatory compliance—the very subject of her report. Defendants also fail to acknowledge that, among other qualifications: Ms. Kuehn co-authored a chapter in the "Bringing Your Medical Device to Market" trade manual, titled "Good Manufacturing and Laboratory Practice for Medical Device Development"; she has spent several years counseling companies seeking to establish quality systems; she counseled clients who have been inspected by the FDA and required revisions to their quality systems to bring the company into compliance with FDA regulations; she has communicated with the FDA regarding identified compliance issues and worked with the FDA to remedy the FDA's concerns; and she is a member of organizations of regulatory affairs professionals, including the Organization of Regulatory and Clinical Associates and the Regulatory Affairs Professional Society. (*See* Briley Decl., Ex. 1 (Kuehn Report) at App. A; Whitney Decl., Ex. G (Kuehn Depo.) at 12:17-21:25, 24:19-27:10.)

[2] In support of their argument that Ms. Kuehn lacks the required knowledge to opine on Quality System Regulations, Defendants cite to *R.F.M.A.S., Inc. v. Mimi So*, 748 F. Supp. 2d 244 (S.D.N.Y. 2010). That case, however, addressed whether various experts' *methods* were reasonable, and specifically noted that "RFMAS's arguments with respect to its experts' *qualifications* are either immaterial or irrelevant." *Id.* at 250 (emphasis added). *R.F.M.A.S.*, therefore, does not support Defendants' position.

Defendants instead state that the "sole basis" for Ms. Kuehn's expertise is her certification through the Regulatory Affairs Professional Society ("RAPS"). (Defs.' Mot. at 1-2.) Defendants deem this certification meaningless because "[a]nyone can become a member of RAPS" and "[a]nyone with a bachelor's degree can take the exam to obtain Regulatory Affairs Certification." (Defs.' Mot. at 2 n.2.) Certainly the same could be said about many professions. That does not mean that everyone—including Defendants' own rebuttal expert—has attained that certification. Although hardly the only basis for Ms. Kuehn's expertise, the Regulatory Affairs Certification ("RAC") is a highly regarded certification and the only such credential in the industry. To achieve certification, an applicant must attend fourteen courses related to regulatory affairs and FDA regulations over a twelve-month period before being able to sit for the exam. (*See* Whitney Decl., Ex. D (RAC Application page) ("A RAC is obtained by passing a rigorous exam and maintained by acquiring continuing education credits within a three-year cycle."); *id.*, Ex. E (RAC Program Details).) Maintenance of RAC requires the accumulation of thirty-six "RAC credits" every three years through continuing education courses, public speaking on regulatory topics, professional writing and involvement with professional organizations in order to obtain recertification. (*See id.*, Ex. F (Maintaining Professional Certification).)

Indeed, courts routinely find that RAC is a meaningful expert qualification. *See In re Celexa and Lexapro Prods. Liability Litigation*, MDL No. 1736, 2013 U.S. Dist. LEXIS 30844, at *16, *16 n.3 (E.D. Mo. Mar. 4, 2013) (denying motion to exclude expert based on expert's education, training and experience, which included RAC, and noting that "RAPS is the largest global organization of and for those involved with the regulation of healthcare and related products, including medical devices, pharmaceuticals, biologics and nutritional products") (quoting http://www.raps.org/); *Woodard v. Stryker Corp.*, No. 11-CV-36-F, 2012 U.S. Dist.

LEXIS 119096, at *21 (D. Wyo. July 16, 2012) ("[T]he U.S. Regulatory Affairs Certification credential, [] is the only certification specifically for regulatory professionals in the healthcare product sector and certifies knowledge of U.S. Regulations."); *Schott v. I-Flow Corp.*, 696 F. Supp. 2d 898, 904 (S.D. Ohio 2010) (denying motion to disqualify where expert worked in the field of FDA regulation, possessed RAC, and was a fellow with the Regulatory Affairs Professional Society).

In other words, Ms. Kuehn is a qualified expert to testify regarding FDA compliance. At the September 27, 2013 pre-motion conference, the Court stated:

> [Ms. Kuehn] says ADI lacked a functioning quality management system prior to the acquisition, that the pre acquisition procedures did not comply with FDA regulations and that ADI failed to engage in risk management activities as required by the FDA. That seems to be relevant to the claims. It's supported, it would be helpful. Obviously, it's not an opinion you like. But I don't see anything wrong with it.
>
> I know your argument that it's a legal conclusion, but I don't think so. She has expertise in this area. She can comment and state that ADI was not in compliance with all applicable laws and regulations between 2006 and 2009. That's what experts do. So I don't see anything wrong with Kuehn either. So that's my views, initial views on all those.

(Whitney Decl., Ex. A (Sept. 27, 2013 Tr.) at 16:16 – 17:4.)

Defendants apparently do not like or agree with Ms. Kuehn's opinion, but that is not a reason to exclude it. Quite the opposite: Defendants' disagreement with Ms. Kuehn's report and the issues they raise go, at most, to the weight, not admissibility, of her testimony.[3] *See*, *e.g.*, *MBIA Ins. Corp. v. Patriarch Partners VIII, LLC*, No. 09 Civ. 3255, 2012 U.S. Dist. LEXIS 92435, at *48 (S.D.N.Y. July 2, 2012) ("Patriarch may appropriately contend that Mason's

[3] Defendants' attempt to rebut Ms. Kuehn's report by attaching nine separate exhibits related to audit reports and a Preliminary Due Diligence Report is flawed in several respects. Nevertheless, the fact that Defendants disagree with Ms. Kuehn's reading, and opinion regarding the relevance, of these reports is not grounds to exclude her expert testimony. In the interest of brevity, and because they are clearly factual issues to be addressed at trial, Plaintiffs have not addressed the shortcomings of Defendants' factual contentions here.

assessments do not support his conclusion, but those contentions will be presented through cross examination and contrary evidence.").

B. Ms. Kuehn's Opinions Are Based on Sufficient Facts and Data.

In addition to her education, experience and knowledge of FDA regulations, Ms. Kuehn's opinions are based on an extensive search for, and review of, relevant documents, and her analysis of those documents. (*See* Briley Decl., Ex. 1 (Kuehn Report) at 2.) Ms. Kuehn's 39-page report cites to more than 300 documents in support of her opinion. (*See id.* at App. B.) She searched through over 100,000 documents to pinpoint the most relevant documents for her analysis, and interviewed company employees to verify her observations and confirm documents that did not exist. (*See* Whitney Decl., Ex. G (Kuehn Depo.) at 63:20 – 64:3 ("I was given access to over a hundred thousand documents and searched very carefully for what I was looking for. And when we did not find what I needed I talked with employees at ADI to verify my observations that documents and compilations of documents were not present that were required under the Quality System Regulation."); *id.* at 62:7-12 ("I did a broad and deep review of their quality system documentation and found that they were non-compliant throughout their quality system, including management responsibilities and management system."). Ms. Kuehn's review of thousands of documents, her interviews with employees and her analysis based on her wealth of experience in the industry are more than sufficient to find that her opinion is reliable.

Defendants' cited authority does not hold otherwise. In *Donnelly v. Ford Motor Co.*, 80 F. Supp. 2d 45 (E.D.N.Y. 1999), for example, the court found that the proposed expert did not base his opinion on sufficient evidence, namely that he did not cite to evidence that a fire started from the ignition of a car, the alleged basis for plaintiff's suit against the car manufacturer. *Id.* at 51. The court also noted that the expert did not cite to industry standards, surveys or studies in his analysis. *Id.* at 50. Unlike the expert in *Donnelly*, Ms. Kuehn's expert report specifically

details her review and analysis conducted to reach her conclusions, and cites to, and explains, the applicable FDA regulations. For example, in her analysis regarding Management Responsibility, Ms. Kuehn discusses her review of the relevant Code of Federal Regulations standard for the FDA, her review of materials received from ADI and the conclusions she reached as a result of analyzing those materials. (*See* Briley Decl., Ex. 1 (Kuehn Report) at 10-13.) Ms. Kuehn supports her conclusions with extensive discussion of ADI's practices and with citations to—and explanations of—industry standards and regulations as well as documents and testimony in this case. This is inapposite to *Donnelly* where the basic foundation of the expert's opinion—where the fire started—was never established.

Defendants are obviously incorrect in stating that Ms. Kuhen's "methodology is premised on missing documents." (Defs.' Mot. at 3 n.3.) Ms. Kuehn relies on—and cites to—hundreds of documents that show FDA compliance violations on their face. While ADI's noncompliant record-keeping practices also factored into her opinion, Ms. Kuehn testified that she spoke to ADI employees to verify that FDA-required documents, such as Corrective and Preventive Action reports and complete Design History Files, did not exist because they were not a part of ADI's compliance procedures. (*See* Whitney Decl., Ex. G (Kuehn Depo.) at 63:20 – 64:3.)[4]

In sum, Defendants identify no supportable basis to disqualify Ms. Kuehn as an expert, and their motion should be denied.

III. Defendants' Counsel's Conspiracy Theory Should Be Disregarded.

Finally, Defendants state—without factual support and based entirely on attorney argument—that because Mr. Ulatowski was retained by Plaintiffs to opine on the 2009 Femtelle

[4] Ms. Kuehn supplemented her report to account for certain documents located in the production that were previously unavailable to her during her initial search due to a processing error with the review database that was provided to Ms. Kuehn. This error was remedied and Ms. Kuehn supplemented her report as required under the Federal Rules.

510(k) and not on FDA compliance, that "can only mean [that Mr. Ulatowski] would disagree with Ms. Kuehn[]." (Defs.' Mot. at 7.) Such a statement is nothing more than an inflammatory and unsupported accusation from Defendants' counsel, and does not merit a response. It is nevertheless sufficient to state that there is no basis for a theory that retaining two experts to opine in two separate areas means anything at all about each expert's views on the other's subject area.

CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court deny Defendants' motion *in limine* to exclude Ms. Kuehn's expert report and testimony.

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